



# Pharmacy



## Medical Necessity Criteria for Phosphodiesterase-5 Inhibitors – Cialis (tadalafil), Levitra (vardenafil), Staxyn (vardenafil ODT)

**Background** - After evaluating the relative clinical and cost effectiveness of the PDE-5 inhibitors for erectile dysfunction, the DoD P&T Committee recommended that Cialis (tadalafil) and Levitra (vardenafil) and Staxyn (vardenafil ODT) be designated as non-formulary. This recommendation has been approved by the Director, TMA. Prior authorization requirements and quantity limits continue to apply to the PDE-5 inhibitors.

**Effective Date:** 18 April 2012

### Medical Necessity Criteria for Cialis, Levitra and Staxyn

The non-formulary cost share for Cialis, Levitra and Staxyn may be reduced to the formulary cost share IF one or more of the following criteria are met:

1. The patient had a hypersensitivity reaction to Viagra
2. The patient has experienced significant adverse effects from Viagra
3. **For a patient previously treated with Cialis, Levitra or Staxyn:** the patient tried Viagra for at least 90 days, titrated to the maximum recommended dose, and experienced significant decrease in erectile function compared to previous therapy.
4. **For a patient not previously treated with Cialis, Levitra or Staxyn:** the patient tried Viagra for at least 90 days, titrated to the maximum recommended dose, and experienced no improvement in erectile function.
5. The patient is being treated with Cialis for pulmonary arterial hypertension (previously referred to as primary pulmonary hypertension).

*Criteria approved through the DoD P&T Committee process November 2011*

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TRICARE Management Activity,  
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# TRICARE Pharmacy Program Medical Necessity Form for Cialis (tadalafil), Levitra (vardenafil), and Staxyn (vardenafil)



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Viagra is the formulary agent of this drug class on the DoD Uniform Formulary at the formulary cost share.** Cialis, Levitra, and Staxyn are non-formulary, but available to most beneficiaries at the non-formulary cost share
- You do NOT need to complete this form in order for non-Active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

<b>MAIL ORDER and RETAIL</b>	<ul style="list-style-type: none"><li>• The provider may <b>call: 1-866-684-4488</b> or the completed form may be <b>faxed to: 1-866-684-4477</b></li><li>• The patient may attach the completed form to the prescription and <b>mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954</b> or <b>email the form only to: TPharmPA@express-scripts.com</b></li></ul>	<b>MTF</b>	<ul style="list-style-type: none"><li>• Non-formulary medications are available at MTFs only if <b>both</b> of the following are met:<ul style="list-style-type: none"><li>◦ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.</li><li>◦ The non-formulary medication is determined to be medically necessary.</li></ul></li><li>• Please contact your local MTF for more information. There are no cost shares at MTFs.</li></ul>
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## Step 1 Please complete patient and physician information (please print):

<b>1</b>	Patient Name: _____	Physician Name: _____
	Address: _____	Address: _____
	Sponsor ID #: _____	Phone #: _____
	Date of Birth: _____	Secure Fax #: _____

## Step 2 Please explain why the patient cannot be treated with the formulary medication. Circle a reason code if applicable. You MUST supply a specific written clinical explanation as to why use of the formulary medication would be unacceptable.

Formulary Medication	Reason	Clinical Explanation
Viagra (sildenafil)	1 2 3 4 5 6 7	

### Acceptable clinical reasons for not using the formulary medication(s) are:

1. Use of the formulary medication is contraindicated.
2. The patient has experienced significant adverse effects from the formulary medication.
3. Use of the formulary medication has resulted in therapeutic failure.
4. The patient is being treated for Raynaud's phenomenon AND use of Viagra has resulted in therapeutic failure.
5. The patient is being treated for the preservation/restoration of erectile function following prostatectomy AND use of Viagra has resulted in therapeutic failure.
6. The patient is being treated with Cialis for signs and symptoms of BPH (benign prostatic hypertrophy).
7. The patient is being treated with Cialis for pulmonary arterial hypertension (PAH).

## Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

**3**

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date